

AMENDMENTS TO THE CLAIMS

Please amend claims as follows:

1. (currently amended) A controlled release composition for oral administration, comprising:

(1) an immediate release pellet comprising:

- (a) venlafaxine, its o-desmethylvenlafaxine active metabolite, ~~isomers~~, or a pharmaceutically acceptable salt thereof;
- (b) an inert sugar pellet; and
- (c) a binder;

(2) an extended release pellet comprising:

(i) a core comprising:

- (a) venlafaxine, its active o-desmethylvenlafaxine active metabolite, ~~isomers~~, or a pharmaceutically acceptable salt thereof;
- (b) an inert sugar pellet; and
- (c) a binder;

(ii) a coating surrounding the core comprising:

- (a) a water-insoluble polymer;

wherein the maximum plasma concentration of venlafaxine is obtained in less than four hours, and said inert pellet has a diameter ranging from about 15 to about 50 mesh.

2. (cancelled).

3. (currently amended) The controlled release composition according to claim [[2]] 1 wherein the maximum plasma concentration of venlafaxine is obtained in about two to about three hours.

4. (previously presented) The controlled release composition according to claim 1 wherein

(1) the immediate release pellet comprises:

- (a) 30-80 % of venlafaxine, its active metabolite, isomer, or

- pharmaceutically acceptable salt thereof;
- (b) 20-70% of an inert pellet; and
- (c) 1-20% of a binder; and
- (2) the extended release pellet comprises:
 - (i) the core comprising:
 - (a) 30-80% of venlafaxine, its active metabolite, isomer, or a pharmaceutically acceptable salt thereof;
 - (b) 20-70% of an inert pellet; and
 - (c) 1-20% of a binder;
 - (ii) the coating and optionally a second coating if employed comprising:
 - (a) 40-99% of a water insoluble polymer;
 - (b) 0-20% of a surfactant;
 - (c) 0-15% of an antisticking agent; and
 - (d) 0-30% of a plasticizer.

5. (previously presented) The controlled release composition according to claim 4 wherein

- (1) the immediate release pellet comprises:
 - (a) 45-70 % of venlafaxine, its active metabolite, isomer, or a pharmaceutically acceptable salt;
 - (b) 30-50% of an inert pellet; and
 - (c) 2-15% of a binder; and
- (2) the extended release pellet comprises:
 - (i) the core comprising:
 - (a) 50-70% of venlafaxine, its active metabolite, isomer, or a pharmaceutically acceptable salt;
 - (b) 30-50% of an inert pellet; and
 - (c) 2-15% of a binder; and
 - (ii) the coating and optionally the second coating if employed comprising:
 - (a) 50-90% of a water insoluble polymer;
 - (b) 0.1-10% of a surfactant;

- (c) 2-10% of an antisticking agent; and
- (d) 0.1-15% of a plasticizer.

6. (cancelled).

7. (original) The controlled release composition according to claim 1, wherein the extended release pellets comprise from about 40-80 % of the composition.

8. (original) The controlled release composition according to claim 7, wherein the extended release pellets comprise from 60-75% of the composition.

9. (original) The controlled release composition according to claim 1, wherein the binder is selected from the group consisting of cellulose esters, cellulose ethers, polyoxides, polyacrylates, polyethylene, polypropylene, polyurethane, hydroxypropyl methylcellulose, hydroxypropyl cellulose, polyvinylpyrrolidone and mixtures of the foregoing.

10. (original) The controlled release composition according to claim 1, wherein the binder is a water insoluble polymer.

11. (original) The controlled release composition according to claim 10, wherein the binder is ethylcellulose.

12. (original) The controlled release composition according to claim 1 wherein the binder is a mixture of water insoluble polymers and water soluble polymers.

13. (original) The controlled release composition according to claim 12 wherein the binder is a mixture of ethylcellulose and polyvinyl pyrrolidone.

14. (original) The controlled release composition according to claim 1, wherein the water-insoluble polymer is selected from the group consisting of polymethacrylate, methacrylic

acid copolymers, methacrylate ester copolymers, acrylic acid, cellulose esters, a cellulose ethers, cellulose ester-ethers or mixtures thereof.

15. (cancelled).
16. (previously presented) The controlled release composition according to claim 4 wherein the second coating is not optional.
17. (cancelled).
18. (original) The controlled release composition according to claim 1 that exhibits the following dissolution profile when tested according to USP XXV with a Type 2 Apparatus at 50 rpm in distilled water at 37°C:
 - 0-55% of the venlafaxine is released after one hour;
 - 20-60% of the venlafaxine is released after four hours;
 - 25-80% of the venlafaxine is released after eight hours; and
 - not less than 50% of the venlafaxine is released after twelve hours.
19. (original) The controlled release composition according to claim 18 having the following dissolution profile when tested according to USP XXV with a Type 2 Apparatus at 50 rpm in distilled water at 37°C:
 - 10-40% of the venlafaxine is released after one hour;
 - 30-50% of the venlafaxine is released after four hours;
 - 35-70% of the venlafaxine is released after eight hours; and
 - not less than 60% of the venlafaxine is released after twelve hours.
20. (previously presented) A method for providing a therapeutic blood plasma concentration of venlafaxine over a twelve hour to twenty four hour period which comprises administering orally to a patient in need thereof, a controlled release formulation as defined in claim 1 that provides a peak plasma blood level of venlafaxine obtained in less than four hours.

21. (original) The method according to claim 20 wherein peak plasma blood level of venlafaxine is obtained in about two to about three hours.

22. (original) The controlled release composition according to claim 1, wherein said composition is in the form of a tablet or capsule.

Claims 23-32 (cancelled).